

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Continuation  
Application of: Stuart D. Edwards Examiner: M. Peffley  
Serial No. : 09/007,237 Group Art Unit: 3739  
Filed : January 14, 1998  
For : GERD Treatment Apparatus and Method

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PRELIMINARY AMENDMENT

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Commissioner of Patents  
and Trademarks  
Washington, D.C. 20231

Sir:

***The Examiner's attention is directed to the Information Disclosure Statement that accompanies this Amendment. The Statement makes of record in this continuation application the documents that are of record in the parent application.***

Please amend the application prior to the first Office Action and calculation of filing fee as follows:

**IN THE SPECIFICATION:**

Please amend the Cross-Related Application paragraph beginning on Page 1, Line 5 as follows in clean form (the amended paragraph is also presented attached in marked-up form):

Continuation Application of  
Serial No. 09/007,237  
Preliminary Amendment

**Clean Version of Amended Paragraph**

This application is a continuation of co-pending US. Patent Application Serial No. 09/007,237, filed January 14, 1998.

**Marked-Up Version of Amended Paragraph**

This application is a continuation of co-pending U.S. Patent Application Serial No. 09/007,237, filed January 14, 1998 [continuation-in-part of U.S. Patent Application Serial No. 08/731,372, filed October 11, 1996, which is a continuation-in-part of U.S. Patent Application Serial No. 08/319,373, filed October 6, 1994, which is a continuation-in-part of U.S. Application No. 08/286,862, filed August 4, 1994, which is a continuation-in-part of U.S. Patent Application Serial No. 08/272,162, filed July 7, 1994, which is a continuation-in-part of U.S. Patent Application Serial No. 08/265,459, filed June 24, 1994, and is related to concurrently filed Application entitled "GERD Treatment Apparatus and Method" identified as Attorney Docket 14800-748, all with named inventor Stuart D. Edwards, and all of which are incorporated herein by reference].

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Preliminary Amendment

In the Brief Description of the Drawings, please amend the paragraph on page 6,  
Lines 22-23 as follows in clean form (a marked-up version of amended sentence is also  
presented attached):

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**Clean Version of Amended Paragraph (Page 6, Lines 22 to 23)**

FIGS. 19a and 19b are views similar to that of FIG. 18 illustrating shrinkage of the lesion site caused by cell infiltration.

**Marked-up Version of Amended Paragraph (Page 6, Lines 22 to 23)**

FIGS. 19a and 19b are [is a] views similar to that of FIG. 18 illustrating shrinkage of the lesion site caused by cell infiltration.

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In the Brief Description of the Drawings, please amend the paragraph on page 7,  
Lines 3-4 as follows in clean form (a marked-up version of amended sentence is also presented  
attached):

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**Clean Version of Amended Paragraph (Page 7, Lines 3 and 4)**

FIGS. 23A-D are lateral views of the esophageal wall illustrating various patterns of lesions created by the apparatus of the present invention.



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**Marked-up Version of Amended Paragraph (Page 7, Lines 3 and 4)**

FIGS. 23A-D [is a] are lateral viewss of the esophageal wall illustrating various patterns of lesions created by the apparatus of the present invention.

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**IN THE CLAIMS:**

Please cancel claims 83-110 as being drawn to a non-elected invention in the parent application.

Please consider the following pending claims 1-82, of which claims 1, 2, 10-18, 27-34, 46, 50, 51, 60-66, 78 and 79 have been amended, as attached in clean form as well as in marked-up form showing changes in the amended claims relative to the previous version of the claims according to 37 C.F. R. §1.121(c)(3):

**Clean Version of Pending Claims 1-82**

1 (Amended). An apparatus, comprising:

an expandable member being sized to be positionable in a sphincter, the expandable member having a deployed state and a nondeployed state, the deployed state sized and applying sufficient force to the sphincter to dilate the sphincter at least 5 mm;

an energy delivery device coupled to the expandable member, the energy delivery device configured to controllably produce lesions of a sufficient size, number and configuration in an interior of the sphincter so as to create a selectable tightening of the sphincter; and

a flexible coupling member coupled to the expandable member, the coupling member including at least one lumen and configured to be maneuverable in a body lumen.

2 (Amended). The apparatus of claim 1, wherein a configuration of the energy delivery device includes a plurality of energy delivery members distributed on a surface of the expandable member, the apparatus further comprising:

at least one aperture disposed on one of the expandable member or the flexible coupling member, the at least one aperture configured to direct a cooling fluid to cool the energy delivery device.

3. The apparatus of claim 2, wherein the plurality of energy delivery members are radially distributed along a surface of the energy delivery device expandable member.

4. The apparatus of claim 2, wherein the plurality of energy delivery members are longitudinally distributed along a surface of the expandable member.

5. The apparatus of claim 1, wherein the energy delivery device covers a portion of the surface of the expandable member.

6. The apparatus of claim 2, wherein the energy delivery device covers substantially all of an exterior surface of the expandable member.

7. The apparatus of claim 1, wherein the expandable member is sized to be

positionable in a sphincter and to allow the energy delivery device to contact a portion of the inner surface of a sphincter.

8. The apparatus of claim 1, wherein the expandable member is sized to be positionable in a sphincter and to allow the energy delivery device to contact all of an inner surface of the sphincter.

9. The apparatus of claim 1, where the energy delivery device is sized to be positionable in the sphincter and non-permanently dilate the sphincter from a contracted state; and

wherein the sphincter returns to a pretreatment contracted state upon a removal of the expandable member from the sphincter.

10 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to form lesions in a muscle tissue underlying a sphincter mucosal layer.

11 (Amended). The apparatus of claim 1, wherein the deployed state is sized and applies sufficient force to the sphincter to dilate the sphincter between 5 and 40 mm and the energy delivery device is configured to dilate one of a lower esophageal sphincter or an adjoining tissue.

12 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions at a fixed depth from a mucosal surface layer of the sphincter of no more than 4 mms.

13 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and minimizes injury to a mucosal and a submucosal layer of the sphincter.

14 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce a frequency of sphincter relaxation.

15 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce a duration of sphincter relaxation.

16 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce a frequency of reflux of stomach contents into an esophagus.

17 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce a frequency of a symptom of reflux of stomach contents into an esophagus.

18 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create the lesions and reduce an incidence of a sequela of reflux of stomach contents into an esophagus.

19. The apparatus of claim 1, wherein the energy delivery device is positioned on an exterior surface of the expandable member.

20. The apparatus of claim 1, wherein the energy delivery device is positioned on an interior surface of the expandable member.

21. The apparatus of claim 1, further comprising:  
a lumen positioned in an interior of the expandable member.

22. The apparatus of claim 1, wherein the expandable member is expandable.

23. The apparatus of claim 1, wherein the expandable member is a balloon.

24. The apparatus of claim 1, wherein the expandable member is made of an expandable material.

25. The apparatus of claim 1, wherein the expandable member is made of a porous material.

26. The apparatus of claim 1, further comprising:  
an electrolytic solution housed in an expanded expandable member.

27 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to deliver energy to promote a fibroblast cell infiltration at a site of the lesions.

28 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to deliver energy to promote a fibroblast growth at a site of the lesions.

29 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to deliver energy that promotes a myofibroblast cell infiltration at a site of the lesions.

30 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of a lower esophageal sphincter without permanently damaging anatomical structures near the lower esophageal sphincter.

31 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of the lower esophageal sphincter without permanently damaging an aorta positioned near the lower esophageal sphincter.

32 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of the lower esophageal sphincter without permanently damaging a vagus nerve positioned near the lower esophageal sphincter.

33 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of the lower esophageal sphincter without permanently damaging an esophageal plexus of nerves and veins positioned near the lower esophageal sphincter.

34 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to create a tightening of the lower esophageal sphincter while preserving a blood supply to the lower esophageal sphincter.

35. The apparatus of claim 1, wherein the energy delivery device is an RF electrode.

36. The apparatus of claim 35, further comprising:  
an RF energy source coupled to the RF electrode.

37. The apparatus of claim 1, wherein the energy delivery device is a microwave antenna.

38. The apparatus of claim 37, further comprising:  
a microwave energy source coupled to the microwave antenna.

39. The apparatus of claim 1, wherein the energy delivery device is a waveguide.

40. The apparatus of claim 39, further comprising:  
a light source coupled to the waveguide.

41. The apparatus of claim 40, wherein the light source is a laser.

42. The apparatus of claim 1, wherein the energy delivery device is an acoustical transducer.

43. The apparatus of claim 1, wherein the energy delivery device is a resistive heating device.

44. The apparatus of claim 1, further comprising:  
a visualization device coupled to the expandable member.

45. The apparatus of claim 1, further comprising:  
an extension member coupled to the expandable member.

46 (Amended). The apparatus of claim 45, wherein a proximal portion of the  
extension member is maneuverable by a medical practitioner.

47. The apparatus of claim 1, wherein the energy delivery device is a plurality of RF  
electrodes.

48. The apparatus of claim 47, wherein the plurality of electrodes is a flexible circuit.

49. The apparatus of claim 1, further comprising:  
a mechanical expansion device coupled to the expandable member.

50 (Amended). An apparatus comprising:

an expandable member means sized to be positionable in a lower esophageal  
sphincter and non-permanently dilate the lower esophageal sphincter from a contracted state,  
the expandable member means having a deployed state and a nondeployed state, the deployed  
state sized and applying sufficient force to the sphincter to dilate the sphincter between 5 and  
40 mm;

an energy delivery device means coupled to the expandable member means, the  
energy delivery device means configured to controllably produce lesions of a sufficient size,  
number and configuration in an interior of the lower esophageal sphincter to create a tightening  
of the lower esophageal sphincter;

a flexible coupling member means coupled to the expandable member means, the  
coupling member means including at least one lumen means and configured to be  
maneuverable in a body lumen; and,

wherein the lower esophageal sphincter returns to a contracted state upon a  
removal of the expandable member means from the sphincter.

51 (Amended). The apparatus of claim 50, wherein the energy delivery device  
means is configured to controllably produce lesions in an interior of the lower esophageal



sphincter without creating a permanent impairment of the lower esophageal sphincter's ability to achieve a physiologically normal state of closure.

52. The apparatus of claim 50, wherein the energy delivery device is positioned on an exterior surface of the expandable member means.

53. The apparatus of claim 50, wherein the energy delivery device is positioned on an interior surface of the expandable member means.

54. The apparatus of claim 50, further comprising:  
a lumen means positioned in an interior of the expandable member means.

55. The apparatus of claim 50, wherein the expandable member means is expandable.

56. The apparatus of claim 50, wherein the expandable member means is a balloon.

57. The apparatus of claim 50, wherein the expandable member means is made of an expandable material.

58. The apparatus of claim 50, wherein the expandable member means is made of a porous material.

59. The apparatus of claim 57, further comprising:  
an electrolytic solution means housed in an expanded expandable member means.

60 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to deliver energy to the interior of the lower esophageal sphincter and create a fibroblast proliferation in the interior of the lower esophageal sphincter.

61 (Amended). The apparatus of claim 50, wherein the energy delivery device

means is configured to deliver energy to the interior of the lower esophageal sphincter and create a myofibroblast proliferation in the lower esophageal sphincter.

62 (Amended). The apparatus of claim 50, wherein [the configuration of] the energy delivery device means is configured to create[s] a tightening of the lower esophageal sphincter without permanently disrupting an aorta positioned near the lower esophageal sphincter.

63 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to create a tightening of the lower esophageal sphincter without permanently damaging a vagus nerve positioned near the lower esophageal sphincter.

64 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to create a tightening of the lower esophageal sphincter without permanently damaging an esophageal plexus of nerves and veins positioned near the lower esophageal sphincter.

65 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to create a tightening of the lower esophageal sphincter while preserving a blood supply to the lower esophageal sphincter.

66 (Amended). The apparatus of claim 50, wherein the energy delivery device means is configured to create a tightening of the lower esophageal sphincter while creating submucosal lesions in the lower esophageal sphincter.

67. The apparatus of claim 50, wherein the energy delivery device means is an RF electrode means.

68. The apparatus of claim 47, further comprising:  
an RF energy source means coupled to the RF electrode means.

69. The apparatus of claim 50, wherein the energy delivery device means is a microwave antenna means.

70. The apparatus of claim 69, further comprising:  
a microwave energy source means coupled to the microwave antenna means.

71. The apparatus of claim 50, wherein the energy delivery device means is a waveguide means.

72. The apparatus of claim 71, further comprising:  
a light source means coupled to the waveguide means.

73. The apparatus of claim 72, wherein the light source means is a laser means.

74. The apparatus of claim 50, wherein the energy delivery device means is an acoustical transducer means.

75. The apparatus of claim 74, further comprising:  
an acoustical energy source means coupled to the acoustical transducer means.

76. The apparatus of claim 50, wherein the energy delivery device means is a resistive heating device means.

77. The apparatus of claim 50, further comprising:  
a visualization device means coupled to the expandable member means.

78 (Amended). The apparatus of claim 50, further comprising:  
an extension member means coupled to the expandable member means.

79 (Amended). The apparatus of claim 78, wherein a proximal portion of the extension member means is maneuverable by a medical practitioner.

80. The apparatus of claim 50, wherein the energy delivery device means is a plurality of RF electrode means.

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81. The apparatus of claim 80, wherein the plurality of electrode means is a flexible circuit means.

82. The apparatus of claim 50, further comprising:  
a mechanical expansion device means coupled to the expandable member means.

**Marked-Up Version of Amended Claims 1, 2, 10-18, 27-34, 46, 50, 51, 60-66, 78 and 79**

1 (Amended). An apparatus, comprising:

an expandable member being sized to be positionable in a sphincter, the expandable member having a deployed state and a nondeployed state, the deployed state sized and applying sufficient force to the sphincter to dilate the sphincter at least 5 mm; [and]

an energy delivery device coupled to the expandable member, the energy delivery device [having a configuration that] configured to controllably produce[s] lesions of a sufficient size, number and configuration in an interior of the sphincter so as to create a selectable tightening of the sphincter[.]; and

a flexible coupling member coupled to the expandable member, the coupling member including at least one lumen and configured to be maneuverable in a body lumen.

2 (Amended). The apparatus of claim 1, wherein [the] a configuration of the energy delivery device includes a plurality of energy delivery members distributed on a surface of the expandable member, the apparatus further comprising:

at least one aperture disposed on one of the expandable member or the flexible coupling member, the at least one aperture configured to direct a cooling fluid to cool the energy delivery device.

10 (Amended). The apparatus of claim 1, wherein the energy delivery device is configured to form lesions [are formed] in a muscle tissue underlying a sphincter mucosal layer.

11 (Amended). The apparatus of claim 1, wherein the [sphincter is] deployed state is sized and applies sufficient force to the sphincter to dilate the sphincter between 5 and 40 mm and the energy delivery device is configured to dilate one of a lower esophageal sphincter or an adjoining tissue.

12 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] the lesions at a fixed depth from a mucosal surface layer of the sphincter of no more than 4 mms.

13 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] the lesions and minimizes injury to a mucosal and a submucosal layer of the sphincter.

14 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] the lesions and reduce[s] a frequency of sphincter relaxation.

15 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] the lesions and reduce[s] a duration of sphincter relaxation.

16 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] the lesions and reduce[s] a frequency of reflux of stomach contents into an esophagus.

17 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] the lesions and reduce[s] a frequency of a symptom of reflux of stomach contents into an esophagus.

18 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] the lesions and reduce[s] an incidence of a sequela of reflux of stomach contents into an esophagus.

27 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to deliver[s] energy to promote a fibroblast cell infiltration at a site of the lesions.

28 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to deliver[s] energy to promote a fibroblast growth at a site of the lesions.

29 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to deliver[s] energy that promotes a myofibroblast cell infiltration at a site of the lesions.

30 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] a tightening of a lower esophageal sphincter without permanently damaging anatomical structures near the lower esophageal sphincter.

31 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] a tightening of the lower esophageal sphincter without permanently damaging an aorta positioned near the lower esophageal sphincter.

32 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] a tightening of the lower esophageal sphincter without permanently damaging a vagus nerve positioned near the lower esophageal sphincter.

33 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] a tightening of the lower esophageal sphincter without permanently damaging an esophageal plexus of nerves and veins positioned near the lower esophageal sphincter.

34 (Amended). The apparatus of claim 1, wherein [the configuration of] the energy delivery device is configured to create[s] a tightening of the lower esophageal sphincter while preserving a blood supply to the lower esophageal sphincter.

46 (Amended). The apparatus of claim 45, wherein a proximal portion of the extension member is maneuverable by a medical practitioner.

50 (Amended). An apparatus comprising:

an expandable member means sized to be positionable in a lower esophageal sphincter and non-permanently dilate the lower esophageal sphincter from a contracted state, the expandable member means having a deployed state and a nondeployed state, the deployed

state sized and applying sufficient force to the sphincter to dilate the sphincter between 5 and 40 mm;

an energy delivery device means coupled to the expandable member means, the energy delivery device means [having a configuration that] configured to controllably produce[s] lesions of a sufficient size, number and configuration in an interior of the lower esophageal sphincter to create a tightening of the lower esophageal sphincter;

a flexible coupling member means coupled to the expandable member means, the coupling member means including at least one lumen means and configured to be maneuverable in a body lumen; and,

wherein the lower esophageal sphincter returns to a contracted state upon a removal of the expandable member means from the sphincter.

51 (Amended). The apparatus of claim 50, wherein the energy delivery device means [has a configuration that] is configured to controllably produce[s] lesions in an interior of the lower esophageal sphincter without creating a permanent impairment of the lower esophageal sphincter's ability to achieve a physiologically normal state of closure.

60 (Amended). The apparatus of claim 50, wherein [the configuration of] the energy delivery device means is configured to deliver[s] energy to the interior of the lower esophageal sphincter and create[s] a fibroblast proliferation in the interior of the lower esophageal sphincter.

61 (Amended). The apparatus of claim 50, wherein [the configuration of] the energy delivery device means is configured to deliver[s] energy to the interior of the lower esophageal sphincter and create[s] a myofibroblast proliferation in the lower esophageal sphincter.

62 (Amended). The apparatus of claim 50, wherein [the configuration of] the energy delivery device means is configured to create[s] a tightening of the lower esophageal sphincter without permanently disrupting an aorta positioned near the lower esophageal sphincter.

63 (Amended). The apparatus of claim 50, wherein [the configuration of] the energy delivery device means is configured to create[s] a tightening of the lower esophageal sphincter



without permanently damaging a vagus nerve positioned near the lower esophageal sphincter.

64 (Amended). The apparatus of claim 50, wherein [the configuration of] the energy delivery device means is configured to create[s] a tightening of the lower esophageal sphincter without permanently damaging an esophageal plexus of nerves and veins positioned near the lower esophageal sphincter.

65 (Amended). The apparatus of claim 50, wherein [the configuration of] the energy delivery device means is configured to create[s] a tightening of the lower esophageal sphincter while preserving a blood supply to the lower esophageal sphincter.

66 (Amended). The apparatus of claim 50, wherein [the configuration of] the energy delivery device means is configured to create[s] a tightening of the lower esophageal sphincter while creating submucosal lesions in the lower esophageal sphincter.

78 (Amended). The apparatus of claim 50, further comprising:  
an extension member means coupled to the expandable member means.

79 (Amended). The apparatus of claim 78, wherein a proximal portion of the extension member means is maneuverable by a medical practitioner.

#### REMARKS

The Specification has been amended to claim continuation status to the co-pending parent U.S. Patent Application Serial Number 09/007,237, filed January 14, 1998. The priority claim originally made in the parent case been also amended to delete continuation status based upon applications filed before the parent case.

The Specification has also been amended to correct typographical errors in the Brief Description of the Drawings, as was entered in the parent application.

This continuation application is being filed for the purpose of adding an additional inventor to the inventor listed in the parent application. More particularly, the inventor David Utley has been added.

A new Terminal Disclaimer is submitted herewith, signed on behalf of the assignee of record Curon Medical, Inc. The assignment is recorded at Reel 011567 and Frame 0469. The Terminal Disclaimer was required by the Examiner during prosecution of the parent application (U.S. Patent Application Serial No. 09/007,237, Examiner M. Peffley, Group 3739). The Assignment to Conway Stuart (renamed Curon Medical, Inc.) of Application Serial No. 09/007,283, filed January 14, 1998, as set forth in the new Terminal Disclaimer, is recorded at Reel 010283 and Frame 0012.

The Terminal Disclaimer filed in the parent case contained a typographical error and a clerical error and is thereby withdrawn. It contained a typographical error in referring to Application Serial No. 09/007,238 instead of Application Serial No. 09/007,283 (the '283 Application). It contained a clerical error in referring to Stuart Edwards as the owner of the parent application and the '283 Application instead of Conway Stuart Medical (now Curon Medical, Inc.).

The Preliminary Amendment also cancels claims 83-110 (which were directed to a non-elected invention in the parent application) and amends claims 1, 2, 10-18, 27-34, 50, 51, 60-66, 78 and 79 to reflect amendments submitted in the parent application.

Claims 1-82 as amended stood allowed in the parent application.

Claims 29, 46, 78 and 79 have been additionally amended to correct typographical errors.

The parent case will be allowed to go abandoned by not paying the Base Issue Fee, due for payment on July 24, 2001.

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Entry of the foregoing Preliminary Amendment and affirmation of the allowance of the claims previously allowed in the parent case are respectfully requested.

Respectfully submitted,

By

  
Daniel B. Ryan

Registration No. 29,243

RYAN KROMHOLZ & MANION, S.C.  
P.O. Box 26618  
Milwaukee, Wisconsin 53226-0618  
(262) 783-1300  
July 24, 2001  
007237pa.CON.ddy